

Message

From: McNally, Robert [McNally.Robert@epa.gov]
Sent: 4/16/2020 3:26:03 PM
To: Mendelsohn, Mike [Mendelsohn.Mike@epa.gov]
CC: Overstreet, Anne [overstreet.anne@epa.gov]; Moyer, Adam [moyer.adam@epa.gov]; Bohnenblust, Eric [Bohnenblust.Eric@epa.gov]
Subject: RE: Current Oxitec Schedule

thanks

From: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Sent: Thursday, April 16, 2020 11:09 AM
To: McNally, Robert <McNally.Robert@epa.gov>
Cc: Overstreet, Anne <overstreet.anne@epa.gov>; Moyer, Adam <moyer.adam@epa.gov>; Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>
Subject: RE: Current Oxitec Schedule

I called Ben and he said he will have reviewed the response to comments document and per the schedule send us comments by Friday COB. Besides OGC, secondary review of the DERs and risk assessment is critical. Regarding the NOI, my understanding is that we will prepare after the 30th. We should be able to publish the FR sometime in May. However, we should also be able to add materials to the docket shortly after issuance.

Mike

From: McNally, Robert <McNally.Robert@epa.gov>
Sent: Thursday, April 16, 2020 10:35 AM
To: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Cc: Overstreet, Anne <overstreet.anne@epa.gov>; Moyer, Adam <moyer.adam@epa.gov>; Borges, Shannon <Borges.Shannon@epa.gov>
Subject: Re: Current Oxitec Schedule

How is OGC doing? Will they be done on Friday? I suspect their timelines and how much comment they give will be critical path. True?

What is schedule for the NOI? I think we had hoped to get all the response to comments done before April 30th, so we could get the FR out much sooner than June 30.

What would that schedule look like?

Thanks

Bob

Sent from my iPhone

On Apr 16, 2020, at 9:20 AM, Mendelsohn, Mike <Mendelsohn.Mike@epa.gov> wrote:

Our current schedule is listed below. As you can see these deadlines are very tight and involve input from John Kough and Chris Wozniak as well. Thanks!

Mike

Anticipated Timeframe for completing task for Oxitec EUP

- 4/10 – complete draft response to comment, especially for critical comments, send comment response and draft risk assessment for OGC review, *comment response was sent to OGC*
- 4/17 –complete initial secondary review human health and ecological risk assessment and any outstanding DERs (provide comments to primary reviewers)
- 4/17 - receive comment from OGC on response to comment
- 4/22 - complete section G review based on final section G submission, complete risk assessment (revisions based on secondary review and have document ready for signature/signed), complete response to comment doc based on OGC comment, draft issuance letter
- 4/24 – Send issuance letter and revised response to comment and documents for management review (DD and OD? Review)
- 4/28 – revise per DD level management review, send to Rick for OD level review
- 4/30 – OD sign off, complete issuance of EUP application